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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,705	01/28/2002	Haruki Yamada	082368-000000US	1019
20350	7590	10/24/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/914,705	<b>Applicant(s)</b> YAMADA ET AL.	
	<b>Examiner</b> Robert A. Zeman	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 4-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-8-2006 has been entered.

***Terminal Disclaimer***

The terminal disclaimer filed on 8-8-2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on copending Application No. 10/363,484 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The amendment and response filed on 8-8-2006 are acknowledged. Claims 1-6, 9 and 11-13 have been amended. Claims 15-17 have been added. Claims 1-17 are pending. Claims 5-14 remain withdrawn from consideration as being drawn to non-elected inventions. Claims 1-4 and 15-17 are currently under examination.

***Claim Rejections Withdrawn***

The provisional rejection of claims 1-4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending

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Application No. 10/363,484 is withdrawn in light of the Terminal Disclaimer filed on 8-8-2006.

***Claim Rejections Maintained***

***35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 15-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Lederer et al. (J. Agric. Food Chem. 1999, Vol. 47, pages 4611 –4620) for the reasons set forth in the previous Office action in the rejection of claims 1-3.

**Applicant argues:**

1. Lederer discloses the claimed 18 carbon hydroxyl unsaturated fatty acids in solvents that are unacceptable for administration to a subject and hence do not meet the limitation of being a “pharmaceutical composition” as required by the amended claims.

Applicant’s arguments have been fully considered and deemed non-persuasive.

As outlined previously, Lederer et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report, attached). The use of the descriptive term “pharmaceutical composition” is deemed to be an intended use and hence does not constitute a claim limitation. Moreover,

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Lederer et al. disclose that the disclosed compositions are being tested in biological systems (see page 4619) which would necessarily require them to be acceptable for administration to a subject. Consequently, Lederer et al. anticipates all the limitations of the rejected claims.

Claims 1-3 and 15-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Quinton et al. (Tetrahedron Letters, 1991, Vol. 32, No. 37, pages 4909-4912) for the reasons set forth in the previous Office action in the rejection of claims 1-3.

**Applicant argues:**

1. Quinton discloses the claimed 18 carbon hydroxyl unsaturated fatty acids in solvents that are unacceptable for administration to a subject and hence do not meet the limitation of being a "pharmaceutical composition" as required by the amended claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

As outlined previously, Quinton et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3. The use of the descriptive term "pharmaceutical composition" is deemed to be an intended use and hence does not constitute a claim limitation. Moreover, Quinton et al. disclose that the biological activities of the disclosed compositions are being tested (see page 4912) which would necessarily require them to be acceptable for administration to a subject. Consequently, Quinton anticipates all the limitations of the rejected claims.

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Claims 1-4 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyaichi et al. (Natural Medicines 1995, Vol. 49 No. 1, pages 24-28) for the reasons set forth in the previous Office action in the rejection of claims 1-4.

**Applicant argues:**

1. Miyaichi discloses the claimed 18 carbon hydroxyl unsaturated fatty acids in solvents that are unacceptable for administration to a subject and hence do not meet the limitation of being a “pharmaceutical composition” as required by the amended claims.

Applicant’s arguments have been fully considered and deemed non-persuasive.

As outlined previously, Miyaichi et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC report). The use of the descriptive term “pharmaceutical composition” is deemed to be an intended use and hence does not constitute a claim limitation. Moreover, as acknowledged by Applicant, Miyaichi et al. disclose the claimed 18 carbon hydroxyl unsaturated fatty acid as one of 21 compounds in the herb “Sanleg”. As said herb comprises the claimed compound and is acceptable for administration to a subject, Miyaichi et al. anticipates all the limitations of the rejected claims.

Claims 1-4 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamberg et al. (Plant Physiology, 1996, Vol. 110, pages 807-815) for the reasons set forth in the previous Office action in the rejection of claims 1-4.

**Applicant argues:**

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1. Miyaichi discloses the claimed 18 carbon hydroxyl unsaturated fatty acids in solvents that are unacceptable for administration to a subject and hence do not meet the limitation of being a "pharmaceutical composition" as required by the amended claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

As outlined previously, Hamberg et al. disclose an 18-carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report) wherein said fatty acid was isolated from *Avena sativa* seed homogenates. The use of the descriptive term "pharmaceutical composition" is deemed to be an intended use and hence does not constitute a claim limitation. Moreover, Hamberg et al. disclose the claimed 18 carbon hydroxyl unsaturated fatty acid as one of compounds of oat seeds. As said seed comprises the claimed compound and is acceptable for administration to a subject, Hamberg et al. anticipates all the limitations of the rejected claims.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the claim to recite "consisting essentially of a purified or synthesized hydroxyl unsaturated fatty acid as a sole active ingredient..." This phrase does not appear in the specification, or original claims as filed. Specifically the terms "consisting essentially of" and "sole active ingredient" do not appear in the specification. The portions of the specification cited by Applicant do not provide a specific basis for this limitation and none is apparent. Therefore this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 recites the limitation "prepared from a medicinal plant" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert Navarro can be reached on (571) 272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ROBERT A. ZEMAN  
PRIMARY EXAMINER

October 19, 2006